



**The American Society for Clinical Nutrition, Inc.**  
THE CLINICAL DIVISION OF THE AMERICAN SOCIETY FOR NUTRITIONAL SCIENCES  
*The American Journal of Clinical Nutrition*



October 29, 2004

Leila G. Saldanha  
Department of Health and Human Services  
Office of Dietary Supplements  
6100 Executive Boulevard  
Rm 3B01, MSC 7517  
Bethesda, MD 20892

Dear Dr. Saldanha:

The American Society for Nutritional Sciences (ASNS) and its clinical division, the American Society for Clinical Nutrition (ASCN), thank you for the opportunity to comment on the proposed definition for bioactive food components. Our members, consisting primarily of PhD's and MD's, are engaged in basic and clinical nutrition research and nutrition education.

We applaud HHS for developing the proposed definition: "Bioactive food components are constituents in foods or dietary supplements, other than those needed to meet basic human nutritional needs that are responsible for changes in health status." However, we do have some concerns with this definition such as:

- How does one define and measure "health status"?
- Should all supplements be included in the definition? Many supplements contain synthetic preparations with racemic mixtures, whereas natural foods generally contain specific optical and geometric isomers. Thus, the efficacy of identical doses of synthetic vs. natural components can vary markedly.

Thus, ASNS and ASCN propose that the definition should be revised to: "Bioactive food components are dietary constituents that elicit physiological effects beyond those associated with essential human nutrition." We define "essential human nutrition" as the currently accepted scientific definitions of nutrient requirements as represented by the Institute of Medicine's Dietary Reference Intakes (DRIs). Our rationale for this revised definition is as follows:

- Effects of components may not always be beneficial
- We are not certain how to define basic human nutrition and therefore prefer substituting the term essential as defined above.

ASNS and ASCN would like to also comment specifically on the following questions that were outlined in your notice.

1. What categories/classes of compounds should be considered as bioactive food components?
  - Traditional foods, dietary supplements containing natural products, and food-based botanicals that provide physiological responses should be considered as bioactive food components.
2. What categories/classes of compounds should not be considered as bioactive food components?
  - Compounds that are not naturally part of a human diet such as synthetic and racemic mixtures other than those that are chemically equivalent, rare minerals, and bioactive compounds from non-food plants (e.g., digitalis), as well as macronutrients, vitamins and minerals at levels required to meet essential nutritional needs should not be considered as bioactive food components.
3. Should essential nutrients be included as bioactive food components?
  - ASNS and ASCN agree that essential nutrients should be classified as bioactive food components when they have physiological effects at levels beyond those required to meet essential nutritional requirements.
4. Should synthetically derived components used in fortified foods and dietary supplements be considered under this definition?
  - As stated above, there are concerns about the lack of activity or potentially adverse effects of optical and geometric isomers that are not normally present in the food supply.

Thank you again for the opportunity to comment on bioactive food components.

Sincerely,



Kathleen Rasmussen, PhD  
President, ASNS



Samuel Klein, MD  
President, ASCN

xc: ASNS and the ASCN Public Affairs Committees